

EXHIBIT 20

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

- HIGHLY CONFIDENTIAL -

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

10 VOLUME II

March 8, 2019

March 8, 2019

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1

2 I N D E X
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4

Testimony of:

5

MICHELE R. DEMPSEY

6

7

By Mr. Janush 427, 736

8

9

By Mr. Barker 579

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11

12 E X H I B I T S
13 -----
14

14 NO.	15 DESCRIPTION	16 PAGE
Janssen		
Dempsey-23	E-mail Thread 4/13/18 Subject, Review Controlled Substance Analytics JAN-MS-05444681-92	427
Janssen		
Dempsey-24	E-mail Thread 6/8/18 Subject, Controlled Substances Project JAN-MS-05444730-37	435

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1		- - -	
2	E X H I B I T S (Cont'd.)		
3		- - -	
4			
5	NO.	DESCRIPTION	PAGE
6	Janssen		
7	Dempsey-25	Controlled Substances Suspicious Order Monitoring Program Questionnaire	446
8		JAN-MS-02960654-19	
9			
10	Janssen		
11	Dempsey-26	Evaluation of the Suspicious Orders Monitoring System For J&J (Woodworth)	455
12		JAN-MS-05444748-63	
13			
14	Janssen		
15	Dempsey-27	E-mail Thread 2/6/18 Subject, Question	489
16		JAN-MS-05444648-65	
17	Janssen		
18	Dempsey-28	E-mail Thread 2/16/18 Subject, Report Change	498
19		JAN-MS-05444781-82	
20			
21	Janssen		
22	Dempsey-29	Evaluation of the Suspicious Monitoring System for J&J	500
23		JAN-MS-05444783-98	
24			

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THE VIDEOGRAPHER: We are
now on the record. My name is
Henry Marte. I'm a videographer
with Golkow Litigation Services.

6

7

Today's date is March 8,
2019, and the time is 10:15 a.m.

8

This videotaped deposition
is being held in Princeton, New
Jersey, in the matter of National
Prescription Opiate Litigation.

12

This is Day 2 of the

deposition of Michele Dempsey.

14

All appearances are noted on
the stenographic record.

16

Will the court reporter
please re-administer the oath.

18

- - -

19

... MICHELE R. DEMPSEY,
having been first duly sworn, was
examined and testified as follows:

22

- - -

23

CONTINUED EXAMINATION

24

- - -

1 BY MR. JANUSH:

2 Q. Hi, Ms. Dempsey. How are
3 you today?

4 A. Good. Thank you.

5 Q. Thank you for appearing for
6 Day 2 of your deposition.

7 When we last broke at the
8 conclusion of the January 22, first date
9 of your deposition, we were talking about
10 the audit that had been performed of
11 your -- or Janssen's suspicious order
12 monitoring system.

13 Do you remember that?

14 A. Yes.

15 Q. And I'm going to mark a new
16 document as Dempsey Exhibit 23.

17 MR. JANUSH: Copies to you,
18 your counsel.

19 (Document marked for
20 identification as Exhibit
21 Janssen-Dempsey-23.)

22 MR. BARKER: Evan, just for
23 clarification, this is a
24 collective exhibit? There are a

1 the HDMA conferences where they have a
2 special track on compliance items like
3 suspicious order monitoring where DEA
4 speaks to distributors.

5 Q. What was your title when you
6 took over responsibilities for Janssen's
7 suspicious order monitoring?

8 A. Director of controlled
9 substance compliance.

10 Q. Okay. And is that still
11 your title today?

12 A. Yes.

13 Q. I'd like to discuss the
14 evolution of the Janssen suspicious order
15 monitoring program in more detail.

16 When you first became
17 involved in Janssen's suspicious order
18 monitoring program, what was your
19 understanding as to when that program
20 came into being?

21 A. I learned that the algorithm
22 that was currently being used was
23 implemented in 2006.

24 Q. Okay. And do you have an

1 understanding as to whether there was a
2 program in place to monitor potentially
3 suspicious orders before that one?

4 A. I was aware that in the
5 previous year there was a manual process.

6 MR. BARKER: Okay. Let's
7 mark as Exhibits 42-A, B, and C.
8 (Document marked for
9 identification as Exhibit
10 Janssen-Dempsey-42-A.

11 (Document marked for
12 identification as Exhibit
13 Janssen-Dempsey-42-B.

14 (Document marked for
15 identification as Exhibit
16 Janssen-Dempsey-42-C.)

17 MR. BARKER: Documents that
18 begin with the Bates Numbers
19 JAN-MS-03741177 running through
20 41200. 42-B is JAN-MS-0374110
21 running through 76, and 42-C is
22 374 -- excuse me, JAN-MS-03741201
23 through 05.

24 BY MR. BARKER:

1 A. Yes.

2 Q. Did DEA give any specific
3 advice relating to your suspicious order
4 monitoring program, including whether
5 there were any deficiencies or
6 improvements that could be made?

7 A. No. And if you look at the
8 end, in closing. He said no --

9 Q. You're saying the end.

10 Where are you looking?

11 A. Page 4.

12 Q. Page 4. Okay.

13 A. Closing.

14 Q. So what is the -- what is
15 closing? What are we talking about here?

16 A. This is what Billy Lane
17 said.

18 Q. Okay. Billy Lane is one of
19 the two DEA agents?

20 A. He was the lead inspector.

21 Q. Okay. So Mr. Lane told you
22 what?

23 A. "No violations of the
24 C.F.R." But he said the audit came out

1 fine.

2 Q. Okay. And again, as
3 Mr. Janush pointed out multiple times
4 before, the suspicious order monitoring
5 regulations are in the C.F.R.s, correct?

6 A. Yes.

7 Q. And then let's go to the top
8 of the next page too, please. It also
9 says, "No actions for their part."

10 Does that mean that there
11 were no violations or any other action
12 taken by the DEA?

13 A. That Billy Lane said that
14 they were not taking any actions.

15 Q. Okay. And BL is Billy Lane?

16 A. Yes.

17 Q. Okay. Did Billy Lane say
18 that he likes coming to facilities like
19 the Kentucky distribution center?

20 A. He says that, "Overall likes
21 coming to places like this."

22 Q. And did he have any comments
23 on your recordkeeping systems?

24 A. We had -- we asked him how

1 Q. Got it. So the subject
2 line, although it says 28 January, 2014,
3 it's actually 2015 --

4 A. Yes.

5 Q. -- as reflected in the body.

6 Okay. And at the top line
7 it says, "The DEA just left, there were
8 no observations."

9 What does that tell you
10 about this particular inspection?

11 MR. JANUSH: Objection.

12 MR. BARKER: Strike that.

13 BY MR. BARKER:

14 Q. Do you have an understanding
15 of what the result of the inspection was
16 on or about January 28th of 2015?

17 A. As it's explained here, that
18 from the time period that they audited,
19 which was August 18, 2014, through that
20 January, all the documentation and all
21 the processes they reviewed, there was --
22 there were no observations. Everything
23 was good.

24 Q. Okay. And if we go to Page

1 inspection that you were just looking at
2 in Exhibit 50?

3 A. The dates match.

4 Q. And what was the result of
5 that inspection by the New Jersey
6 Newark -- strike that.

7 What was the result of the
8 inspection by the Newark, New Jersey
9 office of the DEA at the Franklin
10 distribution center?

11 A. There were zero
12 observations.

13 Q. Okay. You're seeing that
14 here?

15 A. Yes.

16 Q. And what does zero
17 observations mean?

18 A. They did not find any
19 noncompliance during their audit of the
20 FDC.

21 Q. When was the next inspection
22 that occurred of a Janssen facility that
23 you're aware of?

24 A. I am guessing two years

1 communicate that he had any
2 response from DEA.

3 BY MR. BARKER:

4 Q. Okay. And certainly not
5 part of his report, which we saw here in
6 Exhibit 52, correct?

7 A. Right.

8 Q. The result of the inspection
9 was what?

10 A. Zero observations.

11 Q. Zero observations. Meaning
12 that they had no criticisms or
13 corrections for your distribution
14 facility, correct?

15 A. Correct.

16 Q. I'm going to mark as the
17 next exhibit a document beginning Bates
18 JAN-MS-03124010 going through 4011.

19 MR. BARKER: We're marking
20 this as Exhibit 54.

21 (Document marked for
22 identification as Exhibit
23 Janssen-Dempsey-54.)

24 BY MR. BARKER:

1 you for correcting me. Who was the lead
2 investigator?

3 A. B. Morgan Freeman.

4 Q. And who is the other
5 investigator this time?

6 A. Jason Smith.

7 Q. The same one who had been
8 there in 2013, right?

9 A. Yes.

10 Q. Okay. And so this was eight
11 days after the SOP had been provided by
12 Mr. Helfrick, as we saw in Exhibit 53,
13 correct?

14 A. Correct.

15 Q. He provided that on the
16 20th. And now they are back on the 28th?

17 A. Yes.

18 Q. Were there any issues found
19 by the DEA in its follow-up inspection on
20 December 28th of 2017 at the Kentucky
21 distribution center?

22 A. Going to the summary, there
23 were zero observations, no issues.

24 Q. So again, they had no

1 criticisms or comments on what they had
2 been provided, correct?

3 A. Correct.

4 MR. BARKER: Next document
5 that I'm going to provide you was
6 one previously marked at your
7 deposition as Exhibit 19.

8 BY MR. BARKER:

9 Q. It begins with
10 JAN-MS-2987651, running through 7656.

11 Do you have Exhibit 19 in
12 front of you?

13 A. Yes, I do.

14 Q. Do you recall Mr. Janush
15 questioning you about this document?

16 A. Yes, I do.

17 Q. Okay. So I want to direct
18 your attention to the second page of the
19 document. And to the comment for DM-3.
20 Are you DM-3 for purposes of this
21 document?

22 A. Yes.

23 Q. How do you know that?

24 A. It's Dempsey, Michele. My

1

2 CERTIFICATE

3

4

5

I HEREBY CERTIFY that the
witness was duly sworn by me and that the
deposition is a true record of the
testimony given by the witness.

6

7

It was requested before
completion of the deposition that the
witness, MICHELE R. DEMPSEY , have the
opportunity to read and sign the
deposition transcript.

8

9

10

11

Michelle L. Gray

12

MICHELLE L. GRAY,
A Registered Professional
Reporter, Certified Shorthand
Reporter, Certified Realtime
Reporter and Notary Public

13

Dated: March 13, 2019

14

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16

17

(The foregoing certification
of this transcript does not apply to any
reproduction of the same by any means,
unless under the direct control and/or
supervision of the certifying reporter.)

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